

Remarks in Support of Patentability

The specification has been amended to eliminate the typographical error noted by the examiner.

The claims have been amended to eliminate the language to which the examiner rejected as reciting structure not illustrated in the drawings. Accordingly, applicant respectfully submits that no new drawings need to be submitted for this application.

The Examiner rejected claims 1 to 4 and 6 to 8 as being anticipated by US 4,681,566 (Fenton, Jr. et al). In the office action the Examiner opines that Fenton teaches at column 8, lines 50 to 57, a syringe driver housing as claimed in claim 1 of the application.

Claim 1 recites a housing for a syringe driver assembly comprises “..at least two interchangeable covers...”.

The Examiner apparently misread and therefore misunderstood Fenton’s teachings. Nowhere and in no way does Fenton teach a syringe driver housing having two different and separate covers which are interchangeable. Fenton teaches a single cover only (Fenton’s cover 14) which may, in an alternative embodiment, include an element which replaces the selector member 58 (Fenton’s column 8, lines 51 to 52) in the cover 14. Therefore, Fenton teaches only a single cover in any one of the embodiments disclosed.

Any reasonable reading of Fenton’s specification finds that Fenton consistently refers to “the cover member 14” throughout his specification, regardless of the embodiment of Fenton’s invention being described. The variation in the embodiments disclosed by Fenton relates to differing positions of the drive coupler and replacement of the selector member 58, as detailed in Fenton’s column 8, lines 50 through 58.

Fenton makes reference to “with *the cover member 14* in its open position” at column 7, line 45, and further states that “in order to accommodate a larger syringe...*the cover member 14* may be positioned to its open position...as shown in figure 7” (Fenton’s column 8, lines 19 through 23). Fenton further states that “thereafter *the cover member 14* may be positioned in its closed position as shown in figure 9” (Fenton’s column 8, lines 45 and 46).

This consistent use of the singular person in the terminology “the cover member 14” by Fenton, in describing the various embodiments of his apparatus, clearly indicates that Fenton does not disclose or even suggest interchangeable covers for the syringe driver housing of his invention. Further evidence of this is provided by Fenton’s language at Fenton’s column 5, lines 48 and 49, where Fenton states: “as will be described in detail below, when *the cover member 14* is in its first cover position...”. Fenton provides still additional evidence of this in his language “[T]he actuating *cover member 14* is elongated and extends along a cover member axis 14a. The actuating *cover member 14* is pivotally coupled to the base member 12 permitting a range of angular motion of the *cover member 14* with respect to the base member...” in Fenton’s text commencing in column 4, line 69 and extending through column 5, line 5.

Yet additional disclosure regarding his single fixed, pivotally mounted cover member 14 appears where Fenton states that “the link members couple one of the spring puller members with *the actuating cover member 14*. The link members are pivotally coupled to *the actuating cover member 14* about at axis 50 which is parallel to the cover axis 24...”; this language appears at Fenton’s column 5, lines 30 through 33.

Fenton provides still further evidence that he envisions only a single cover member, pivotally connected in a permanent manner to the remainder of the syringe driver housing, when he states “*the cover member* is positionable between first and second cover positions with the

first (or open) cover position being shown in figure 2 where *the cover member 14* is maximally angularly displaced with respect to the cavity axes and the second (or closed) cover position shown in figure 1 where *the cover member 14* is minimally angularly displaced with respect to the cavity axes”; this language appears in Fenton’s column 5, lines 40 through 47.

From all of the foregoing, there cannot be any doubt that Fenton does not disclose or even remotely suggest interchangeable covers for his syringe driver housing. Accordingly, applicant respectfully submits that the examiner’s reliance on Fenton, in support of the 35 USC 102 rejection of the claims directed to the syringe driver housing having separate interchangeable covers, is misplaced.

The advantage of the syringe driver housing of the present invention, having two interchangeable covers, is that it provides a simple and relatively inexpensive syringe driver which is capable of accommodating different sizes of syringe. Notwithstanding that Fenton is silent in relation to a syringe driver having two interchangeable covers, as mentioned above, Fenton teaches (column 8, lines 51 to 52) that “the selector member 58 may be replaced by an element in the cover member 14...”. Fenton does not elaborate on what the “element” may be. As the “element” replaces the “selector member 58” we can therefore infer that the element functions in the same manner as the selector member 58 (i.e. it functions to select one of two driving forces (column 7, line 17 to column 8 line 45)). This also corresponds with the function of the “element” in the cover of the alternative embodiment, i.e. “...a syringe may be positioned within the infusion device 10, and driven with a selectable one of two driving forces..” (column 8, lines 58 to 62). Therefore, the function of the alternative embodiment which Fenton teaches is to replace the selector 58, positioned in the base member 12, of a first embodiment, with a similar functioning element which is positioned in the cover of an alternative embodiment. This

provides a mechanism which is at least as complex as the selector member 58 and would be relatively expensive to manufacture and assemble. That is to say, it teaches away from the advantages (simplicity and relatively inexpensive) of the syringe driver as claimed in claim 1.

Further, the invention as defined by claim 1 provides for a modular housing system for receiving the components of a syringe driver assembly that is capable of being quickly adapted to accommodate syringes of different lengths and also provides for a housing that is as small as possible given the dimensions of the syringe (see paragraph 034 of the Patent Cooperation Treaty application as published). The syringe driver taught by Fenton does not in any way provide for these advantages and is incapable of doing so as it is concerned and functions only to select and apply one of two different driving forces, depending on the volume of the syringe. In other words, Fenton is silent in relation to accommodating different lengths of syringe.

Furthermore, notwithstanding the above-mentioned comments, claim 1 also recites (referring to Figure 10) “....wherein the second cover provides for an extension to the body part, the second cover having a longitudinal cross-section in the general form of a hook comprising a long arm and a tail, the long arm forming the cover for laying over the syringe and the tail forming the extension for mating with the main body part”.

The Examiner is of the opinion that “...the second cover is “similar” to the cover shown in Figure 2 [of Fenton]...”. It is submitted that an invention, as claimed, cannot be considered to have been anticipated by an earlier disclosed product or patent which is merely “similar”; the earlier disclosed product or patent must unequivocally have all the features claimed in order to destroy the novelty of a claim. Having said that, the second cover of the claimed invention is in any case clearly very different compared with the cover 14 taught by Fenton, both with regard to its features and function. The cover 14 taught by Fenton (see Fenton’s Figure 2) does not provide

for an extension to accommodate a longer syringe, nor is there any teaching in Fenton's description to suggest that it may do so.

Although the Examiner has endeavoured to describe the cover taught by Fenton as one which is hook shaped, it is clearly not hook shaped, and consequently it is not capable of functioning in a manner which is capable of replacing cover 202, as recited in claim 1. More specifically, the second cover 202, as claimed, is in the shape of a hook having a long arm forming the cover and a tail forming the extension for mating with the main body part.

The term "in the general form of a hook" is commonly understood to mean of a curved nature. Therefore, the second cover, as claimed in claim 1, must by definition have a curved longitudinal axis. The cover 14 and tail, as taught by Fenton (see Fenton's Figure 2), do not, in any way, have curved longitudinal axes. Firstly, they have separate longitudinal axes and secondly the longitudinal axis of the long arm (cover 14) and the tail (the portion of 14 which is attached to the base) are both straight. In no way can they be construed to be curved and therefore they are not in the general form of a hook. Moreover, Fenton does not disclose a second cover having a tail (the portion of 14 which is attached to the base) which is mated with the base. Instead, Fenton discloses a cover 14 which is pivotably coupled 24 (hingedly mounted) to the base 12 and therefore must be mated with pivot means and not the base.

Claim 7 relates to the cover being hingedly mounted (i.e. pivotably coupled) and therefore as claim 7 is dependent on claim 6, by definition, the term "mating", in claim 1, must relate to joining of the cover and base by means other than hinges. The remainder of the claims are either directly or indirectly dependent on claim 1 and therefore they are also both novel and inventive over Fenton.

Claim 6 has been amended to improve the clarity of the claims by incorporating language as respecting the first and second covers, each being “one of the interchangeable” covers and is believed to be patentably distinguishable over Fenton for the reasons set forth above regarding claim 1.

Claims 7 and 9 have been amended to depend from claim 6 and further limit the interchangeable covers. Claims 8, 10 and 11 have been cancelled.

New claim 12 has been added to claim the invention in slightly different form. Claim 12 is clearly distinguishable over Fenton as reciting the presence of “at least two interchangeable covers for attachment to the body” and further reciting that a second one of the interchangeable covers includes “a straight portion” and “a curved portion adjoining the straight portion”. Claim 12 further includes the limitation that the body has a portion for supporting a syringe with “an exterior end of the body being curved” and with the second one of the interchangeable covers having a “curved portion extending laterally from the straight portion and, when the second cover is connected to the body, fitting complementarily about the curved exterior end of the body”. This structure is neither disclosed nor even remotely suggested by Fenton. Accordingly, claim 12 is patentably distinguishable over Fenton.

New claims 13 and 14 add further limitations to the interchangeable covers.

New claim 15 has been added to more clearly address the embodiment of the invention illustrated in Figures 1 through 8. Claim 15 recites in addition to the body portion of the housing, “a member adapted to attach to the body at one end thereof, having a sidewall portion extending perpendicularly from the member for adjoining the sidewall of the body, to provide an extension of the body syringe support region to support with the body a syringe that is longer than the syringe support region of the body.” Fenton does not suggest any such extension

member, providing any extension of the body syringe support region as recited in new claim 15. Accordingly, claim 15 is believed to be patentably distinguishable over Fenton. Claims 16, 17 and 18 add further limitations to claim 15 and are similarly believed to be patentably distinguishable over Fenton.

Claim 19 has been added to more clearly address the kit aspect of the invention and recites the kit having “at least two interchangeable covers, both being adapted for hinged attachment to the body part, each cover being attachable in the absence of the other covers”; this language alone patentably distinguishes claim 19 over Fenton for the reason set forth above regarding claim 1. Claim 19 yet further includes language reciting that the kit includes “a second cover providing an extension from the body and shape to the general form of a hook having a long straight arm and a curved tail, with the long arm forming a cover for laying over the syringe and the tail forming an extension for mating with the body to facilitate support of a syringe longer than the body, to provide a closed housing covering the longer syringe when the second cover is connected to the body”. This additional recitation of structural limitations for the second interchangeable cover further patentably distinguishes claim 19 over Fenton.

Applicant is confused by the examiner’s comments appearing under the heading “Priority” on page 3 of the official action. In that section of remarks, the examiner asserts that if applicant desires to claim the benefit of a prior filed application under 35 USC 371, a specific reference to the prior filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence of the specification filing a title or in an application data sheet.

Applicant submitted an application data sheet, including the relevant priority information, with applicant’s papers filed in the United States Patent and Trademark Office on 9 June 2006 requesting entry into the national phase of proceedings for this application under 35 USC 371. A

copy of that two page application data sheet, which is identified as applicant's document PH2 260001v1 06/09/06, is attached to this paper as Exhibit 1.

The application data sheet as filed in the United States Patent and Trademark Office by applicant on 9 June 2006 was a 2 page application data sheet. Unfortunately, that application data sheet erroneously listed one of the inventor's names three times, rather than listing each of the three inventors' names once.

Shortly after submission of the papers to enter the national phase of proceedings under 35 USC 371, applicant discovered the error in the application data sheet and on 30 June 2006 applicant submitted a corrected application data sheet, again including the property priority claim information, and listing each one of the three inventors by the inventor's correct name. This is a applicant's document PH2 262466 v1 06/30/06. A copy of this revised and correct application data sheet is attached hereto as Exhibit 2.

Further attached hereto as Exhibit 3 is a photocopy of the official filing receipt issued for this application on which under the heading "Domestic Priority Data as Claimed by Applicant" appears the statement "This application is a 371 of PCT GBO4/05195 12/08/2004." There is further listed under the heading "Foreign Applications" United Kingdom application 0328556.6 dated 9 December 2003 and United Kingdom application 0414480.4 dated 29 June 2004. A photocopy of this official filing receipt is attached hereto as Exhibit 3.

In light of the foregoing, Applicant respectfully submits that applicant has met all of the requirements for claiming the benefit of the prior filed Patent Cooperation Treaty application and the benefit of the two United Kingdom applications on which the Patent Cooperation Treaty application is based. Applicant respectfully requests confirmation that applicant has properly claimed the benefit of these earlier filing dates, that applicant is entitled to the benefit of those

earlier filing dates and that the implication, set forth in the heading under "Priority" in Paragraph 2 of the official action, that applicant has somehow not claimed the benefit of any prior application, is incorrect and should be stricken from the record. Applicant further respectfully submits that applicant should not be required to amend the first sentence of the specification in light of applicant's prior submission of an application data sheet for this application.

Confirmation of this is also requested.

Applicant respectfully submits the foregoing addresses all matters outstanding in connection with this application and that upon reconsideration of the application in light of the foregoing, the examiner should withdraw the extant objections and objections of the application and issue a notice of allowance therefor. The same is respectfully solicited.

In the event there are any additional fees required in connection with submission of this paper, please charge those fees to deposit account 50-1943.

Respectfully submitted,

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